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UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

GORDIAN MEDICAL, INC.,

Plaintiff,

v.

KATHLEEN SEBELIUS, Secretary, Department of Health and Human Services,

Defendant.

No. CV 10-3933 CAS (FFMx)

DEFENDANT'S PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

DATE: January 6, 2012

TIME: 9:30 a.m.

PLACE: Courtroom of the Honorable Christina A. Snyder

This action under 42 U.S.C. §§ 405(g), 1395ff(b)(1)(A) for judicial review of a final decision by Kathleen Sebelius, Secretary of Health and Human Services (the "Secretary") came on regularly for trial on January 6, 2012. The Court makes the following findings of fact and conclusions of law:

FINDINGS OF FACT

I. STATUTORY AND REGULATORY BACKGROUND

A. The Medicare Program

1. The Medicare statute, 42 U.S.C. § 1395 et seq., sets forth a federal health insurance program for the elderly and disabled. This cases arises under Part B, which is a voluntary program subsidized by enrollee premiums and appropriated monies. Id. §§ 1395j, 1395o, 1395r, 1395t. Part B provides reimbursement for covered "medical and other health services," which include physician services and some durable medical equipment ("DME"), prosthetics, orthotics, and supplies (collectively, "DMEPOS"). Id. §§ 1395k(a)(1), 1395m(j)(5), 1395x(s)(1), (2)(A), (6), (8), & (9). As pertinent here, certain surgical dressings are among the medical supplies that potentially qualify for Part B coverage. Id. §§ 1395m(j)(5)(D), 1395x(s)(5); 42 C.F.R. § 410.36(a)(1).

2. The statute bars payment for all items and services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). The Secretary has broad authority to explicate the "not reasonable and necessary" coverage exclusion and other coverage provisions in case-specific adjudications or through generally applicable rules that may be established by notice and comment rulemaking or in less formal guidance. Heckler v. Ringer, 466 U.S. 602, 617 (1984); Maximum Comfort, Inc. v. Sec'y of Health and Human Servs., 512 F.3d 1081, 1084 (9th Cir. 2007).

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3. The Secretary, through the Centers for Medicare & Medicaid Services ("CMS"), contracts with private insurance companies to administer the Part B claims process. 42 U.S.C. §§ 1395u, 1395kk-1. DMEPOS benefit claims are administered by four DME Medicare Administrative Contractors ("DME MACs") (formerly known as DME Regional Carriers or "DMERCs"). Id. §§ 1395m(a)(12), 1395kk-1; 42 C.F.R. §§ 421.200, 421.210(b), 421.404(c)(2).

4. Medical supplies and other items of DMEPOS must be furnished "incident to a physician's service" or by a "supplier" that possesses both a valid Medicare supplier number and "billing privileges." 42 U.S.C. §§ 1395m(j)(1), 1395x(d); 42 C.F.R. § 424.57. The supplier's claim must include the appropriate billing code from the Healthcare Common Procedure Coding System ("HCPCS") Level II codes. 45 C.F.R. §§ 162.1000(a), 162.1002(b)(3). See also id. §§ 160.103, 162.100.

5. If a Medicare beneficiary or any assignee of the individual's benefit claim is dissatisfied with a reimbursement determination, the statute and regulations afford several levels of administrative review and, potentially, judicial review. 42 U.S.C. § 1395ff; 42 C.F.R. Part 405, Subpart I. Upon receipt of a claim for payment, the Medicare contractor issues an "initial determination" addressing whether the item or service is covered and meets all other payment requirements, and, if so, the amount deemed owing. 42 U.S.C. § 1395ff(a)(1); 42 C.F.R. § 405.920. If the claimant is dissatisfied with the initial determination, a "redetermination" may be requested by the same contractor. 42 U.S.C. § 1395ff(a)(3); 42 C.F.R. § 405.940. Next, if the claimant is not satisfied with the contractor's redetermination, a "reconsideration" may be requested by a "qualified independent contractor" ("QIC"). 42 U.S.C. § 1395ff(b)(1)(A) & (C); 42 C.F.R. § 405.960. A still dissatisfied claimant may then request a hearing, "as provided in [42 U.S.C. §] 405(b)," before an administrative law judge ("ALJ"). 42 U.S.C. § 1395ff(b)(1)(A), (E) & (d)(1); 42 C.F.R. § 405.1002.

The ALJ's decision may be reviewed by the Medicare Appeals Council ("MAC") of the Departmental Appeals Board. 42 U.S.C. § 1395ff(d)(2); 42 C.F.R. § 405.1100.

6. If dissatisfied after the above administrative appeals process, as here, the claimant may also seek judicial review, "as provided in [42 U.S.C. §] 405(g)," of the final agency decision of the ALJ or the MAC. 42 U.S.C. § 1395ff(b)(1)(A), (E); 42 C.F.R. § 405.1136.[1]

B. The Claims at Issue

7. Plaintiff Gordian Medical, Inc. ("Gordian") is a Medicare enrolled supplier of wound care supplies, including non-bordered composite dressings. (Gordian's Complaint [Dkt. 1] ("Compl.") at ¶¶ 7, 8; Defendant's Answer to Complaint [Dkt. 17] ("Answer") at ¶¶ 7, 8.) Gordian is the successor-in-interest to another Medicare supplier, American Medical Technologies, Inc. (Compl. at ¶ 7.)

8. Medicare coverage of surgical dressings was addressed in the Medicare contractor's Local Coverage Determination (LCD) for Surgical Dressings L11449. In September 2006, the contractor issued a Bulletin Article notifying Medicare suppliers of a revision to the definition of "composite dressings," which was effective October 1, 2006. Under the revised definition, the requisite "bacterial barrier" for a composite dressing must encompass the entire dressing pad including an adhesive border. The Bulletin Article further provided that the HCPCS Level II codes for

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[1] In addition to the foregoing provisions for administrative and judicial review of individual benefit claims, separate appeal provisions apply to a facial challenge to a CMS national coverage determination ("NCD") or a Medicare contractor's local coverage determination ("LCD"). An "aggrieved party" may request review of an NCD by the Departmental Appeals Board ("DAB"), and the DAB's final decision is subject to judicial review. 42 U.S.C. § 1395ff(f)(1); 42 C.F.R. Part 426, Subpart E. Also, an aggrieved party may request review of an LCD by an ALJ; the ALJ's decision is reviewable by the DAB; and the final decision of the ALJ or the DAB, as applicable, is subject to judicial review. 42 U.S.C. § 1395ff(f)(2); 42 C.F.R. Part 426, Subpart D.

composite dressings without adhesive borders, A6200, A6201, and A6202, were invalid for purposes of Medicare claims submission. The Bulletin Article also provided that such non-bordered composite dressings should be billed as specialty absorptive dressings without adhesive border under different HCPCS Level II codes, A6251, A6252, and A6253.[2]

9. In July 2007, CMS issued a HCPCS Quarterly Update providing that, effective July 1, 2007, composite dressings billed under HCPCS codes A6200, A6201, and A6202 "are non-covered by Medicare." CMS Manual System, Pub. 100-4, Medicare Claims Processing Manual, Transmittal 1388 (Dec. 7, 2007).

10. Gordian, however, continued to submit reimbursement claims under HCPCS codes A6200, A6201, and A6202. (Administrative Record ("A.R.") 403-42.) Gordian used those billing codes in claiming reimbursement for dressings supplied to nine Medicare beneficiaries during a three-month period (between December 2007 and February 2008). (A.R. 11.)[3] The Medicare contractor denied those reimbursement claims. (See Compl. at ¶ 33; A.R. 301-02.)

11. Gordian timely appealed those claim denials, but it received adverse redeterminations by the original Medicare contractor, (A.R. 320-89); adverse reconsiderations by the QIC, (A.R. 313-18); and an adverse decision by an ALJ

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[2] The Medicare contractor later issued a Policy Article that incorporated the September 2006 Bulletin Article's revised definition of "composite dressings" and the invalidation of HCPCS codes A6200, A6201, and A6202 for purposes of Medicare claims submission.

[3] Gordian alleges that it also submitted some reimbursement claims under the HCPCS Level II codes for specialty absorptive dressings, A6251, A6252, and A6253, (Compl. at ¶ 59), which are the codes the Medicare contractor's September 2006 Bulletin Article instructed suppliers to use. Those claims are not at issue in this action, however, as Gordian alleges that those claims are still pending in the administrative appeals process. (Id.)

following an "on-the-record" hearing. (A.R. 163-74.) The MAC then issued the final decision of the Secretary. The MAC sustained the denials of coverage based on CMS' July 2007 HCPCS Quarterly Update. (A.R. 3-11.)

12. On May 25, 2010, Gordian filed this record review action seeking relief under the Medicare statute and the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 551 et seq. and 701 et seq. (Compl. at ¶¶ 4, 5.) Gordian seeks reimbursement in accordance with the prior definition of "composite dressings" and the fee schedule payment amounts for HCPCS codes A6200, A6201, and A6202. (Id. at pp. 20-21.) Gordian alleges matters beyond the scope of the MAC's final decision, i.e., that the Secretary unlawfully revised the definition of "composite dressings" and invalidated HCPCS codes A6200, A6201, and A6202 for purposes of Medicare claims submission. (Id. at ¶¶ 70-87.)

CONCLUSIONS OF LAW

A. Standard of Review

1. Subject matter jurisdiction over Gordian's challenge to the Secretary's final decision is based on the Medicare statute, 42 U.S.C. § 1395ff(b)(1)(A), which authorizes judicial review "as provided in [42 U.S.C. §] 405(g)." On review, the Secretary's findings "as to any fact, if supported by substantial evidence, shall be conclusive . . ." Id. § 405(g). Also, judicial review of the Secretary's final decision must be based solely on the administrative record. See id. See also 5 U.S.C. § 706.

2. Under 42 U.S.C. § 405(g), the court must affirm the findings of the Secretary "if they are supported by 'substantial evidence' and if the proper legal standards were applied." Mayes v. Masanari, 276 F.3d 453, 458-59 (9th Cir. 2001). "'Substantial evidence' is more than a mere scintilla but less than a preponderance; it is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." Id. at 459 (internal quotation and citation omitted). Whether substantial evidence supports a finding is determined from the administrative record as a whole,

with the court weighing both the evidence that supports and the evidence that detracts from the Secretary's conclusion. Sandgathe v. Chater, 108 F.3d 978, 980 (9th Cir. 1997). In applying the substantial evidence standard, "a reviewing court may not substitute its own judgment for that of the agency." Memorial, Inc. v. Harris, 655 F.2d 905, 912 (9th Cir. 1980) (citing Citizens to Protect Overton Park, Inc. v. Volpe, 401 U.S. 402, 416 (1971)). Thus, "[w]hen the evidence rationally can be interpreted in more than one way, the court must uphold the [Secretary's] decision." Mayes v. Masanari, 276 F.3d at 459. See also Memorial, Inc. v. Harris, 655 F.2d at 912 ("A finding supported by substantial evidence must be affirmed . . . even if it is possible to draw two inconsistent conclusions from the evidence.") (citation omitted).

3. Under the APA, the reviewing court must affirm the agency's determination unless it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). "A decision is arbitrary and capricious if the agency 'has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.'" O'Keefe's, Inc. v. U.S. Consumer Prod. Safety Comm'n, 92 F.3d 940, 942 (9th Cir. 1996) (quoting Motor Vehicle Mfr.'s Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983)). "This is . . . a highly deferential standard which presumes the validity of the agency's action." Natural Res. Def. Council v. EPA, 16 F.3d 1395, 1400 (4th Cir. 1993). Because agency action is presumed valid, the burden is on the party challenging the agency's action to show that it is arbitrary and capricious; the agency has no obligation to establish that its action is not arbitrary and capricious. Short Haul Survival Comm. v. United States, 572 F.2d 240, 244 (9th Cir. 1978). Deference is all the more warranted here because Medicare is a "complex and highly technical regulatory program" in which "the identification and classification of relevant criteria necessarily require significant expertise, and entail

the exercise of judgment grounded in policy concerns." Thomas Jefferson University v. Shalala, 512 U.S. 504, 512 (1994). Thus, "if a statute or regulation is silent or ambiguous, . . . [the court] will defer to the agency's interpretation unless an alternative reading is compelled by the plain language of the regulation or by other indications of the agency's intent at the time it promulgated the regulation." Foothill Presbyterian Hosp. v. Shalala, 152 F.3d 1132, 1134 (9th Cir. 1998). See also United States v. Elias, 269 F.3d 1003, 1010 (9th Cir. 2001) (if an agency's interpretation "is reasonable, we must defer to the agency's interpretation, even if we would have reached a different result had we construed the statute initially").

B. Judicial Review Is Limited to the Secretary's Final Decision on Gordian's Claims for Nine Beneficiaries During a Three-Month Period.

4. The Medicare statute provides for "judicial review of the Secretary's final decision . . . as is provided in section 405(g) of this title." 42 U.S.C. § 1395ff(b)(1)(A).[4] The Supreme Court and the Ninth Circuit have held that, by virtue of 42 U.S.C. §§ 405(h), 1395(ii), the applicable jurisdictional provisions of the Medicare statute are the exclusive basis for judicial review of all aspects of disputes about Medicare coverage and reimbursement. See, e.g., Heckler v. Ringer, 466 U.S. 602, 610 (1984) (42 U.S.C. § 405(g), as incorporated by 42 U.S.C. § 1395ff(b), provides the sole basis for review of Medicare beneficiaries' challenge to coverage ruling); Queen of Angels/Hollywood Presbyterian Med. Ctr. v. Shalala, 65 F.3d 1472, 1481 n. 23 (9th Cir. 1995) (Medicare hospitals' reimbursement claims are reviewable exclusively under 42 U.S.C. § 1395oo(f)). Thus, since "[f]ederal courts have jurisdiction over Medicare provider reimbursement disputes only to the extent provided by" the Medicare statute, Anaheim Memorial Hospital v. Shalala, 130 F.3d 845, 853 (9th Cir. 1997), a party can secure judicial review of a particular claim or

[4] Gordian alleges subject matter jurisdiction solely on the basis of the Medicare statute, 42 U.S.C. § 405(g). (Compl. at ¶ 5.)

issue under the Medicare statute only if there is a final agency decision on the matter in question.

5. Gordian asserts that "the entire universe of claims" are at issue in this action. (Pl. Op. Brf. [Dkt. 53] at 11 n. 8). However, Gordian also alleges that the "entire universe of claims . . . are [pending] at various stages of administrative appeal." (Compl. at ¶59.) Gordian's allegations of subject matter jurisdiction over all of its claims are not supportable. The MAC's March 24, 2010 final decision is limited to the claims of only nine Medicare beneficiaries during a three-month period. (A.R. 3-11.) In this case, the Court's § 405(g) jurisdiction does not extend beyond the claims of the nine beneficiaries for a three-month period that were denied coverage in the MAC's March 24, 2010 final decision. Heckler v. Ringer, 466 U.S. at 610 (§ 405(g) jurisdiction over Medicare beneficiaries' coverage claims is foreclosed by the absence of a final agency decision on such claims). See also Pacific Coast Med. Enter. v. Harris, 633 F.2d 123, 138 (9th Cir. 1980) (§ 1395oo(f) jurisdiction is limited to Secretary's final decision on Medicare provider's 1973 cost report, and does not extend to later cost reports not subject of a final agency decision); Anaheim Mem'l Hosp. v. Shalala, 130 F.3d at 853 (§ 1395oo(f) jurisdiction is limited to one issue resolved by Secretary's final decision, a decision that did not address provider's equitable tolling claim).

6. The "final decision" requirement in 42 U.S.C. § 405(g) is a "statutorily specified jurisdictional prerequisite," not "simply a codification of the judicially developed doctrine of exhaustion." Weinberger v. Salfi, 422 U.S. 749, 766 (1975). As the Ninth Circuit has explained, the exclusive jurisdictional prerequisites of the Medicare statute consist of two requirements: "a nonwaivable requirement that 'a claim for benefits shall have been presented to the Secretary;'" and a final decision or exhaustion requirement, which "a district court cannot waive . . . for equitable or other policy reasons." Queen of Angels/Hollywood Presbyterian Med. Ctr., 65 F.3d at 1482 (citations omitted). Given Gordian's allegations that most of its claims are

still pending in the administrative appeals process, (Compl. at ¶59), "it cannot be said that the Secretary has in any sense waived further exhaustion" as to whether those claims satisfy the applicable coverage requirements. Heckler v. Ringer, 466 U.S. at 618. Compare Queen of Angels/Hollywood Presbyterian Med. Ctr., 65 F.3d at 148-83 (upholding Secretary's express waiver of exhaustion).

C. The Secretary's Final Decision Is Supported by Substantial Evidence.

7. In the March 24, 2010 final agency decision at issue, (A.R. 3-11), the MAC found that Gordian's Medicare reimbursement claims for surgical dressings furnished to nine beneficiaries during a three-month period (from December 18, 2007 through February 22, 2008) were controlled by CMS' July 2007 HCPCS Quarterly Update. The MAC also found that Gordian billed the composite dressing claims at issue under three HCPCS Level II codes, A6200, A6201, and A6202. As the MAC recognized, however, CMS' July 2007 HCPCS Quarterly Update provides that, effective July 1, 2007, surgical dressings billed under those three HCPCS codes are not covered by Medicare. Therefore, the MAC finally denied coverage of the surgical dressing claims that Gordian billed under the three HCPCS codes.

8. The Court finds that the MAC's March 24, 2010 final decision is supported by substantial record evidence. Gordian billed the composite dressings at issue with three HCPCS Level II codes (A6200, A6201, and A6202) that, under the plain terms of CMS' July 2007 HCPCS Quarterly Update were "non-covered by Medicare, effective July 1, 2007." (CMS Transmittal 1388 at 5.) Moreover, the disputed surgical dressings were furnished to nine beneficiaries between December 18, 2007 and February 22, 2008, whereas CMS' July 2007 HCPCS Quarterly Update became effective four months earlier, on July 1, 2007.

9. Gordon argues that the ALJ's decision on the same claims for the nine beneficiaries is unlawful. (See Pl. Op. Brf. at 13-15.) Gordian also criticizes the QIC's reconsideration and the original contractor's redetermination on the same claims for the nine beneficiaries. (See id. at 9-11.) However, Gordian's complaints

about the ALJ's decision and the prior reconsideration and redetermination by the Medicare contractors are inconsequential; only the final decision by the MAC on the same claims for the nine beneficiaries (during the three-month period) is at issue in this action. See, e.g., Homan & Crimen, Inc. v. Harris, 626 F.2d 1201, 1205 (5th Cir. 1980) ("the decision of the PRRB carries no more weight on review . . . than any other interim decision made along the way in an agency where the ultimate decision of the agency is controlling").[5] See also St. Francis Hosp. Center v. Heckler, 714 F.2d 872, 874 (7th Cir. 1983) (same).

10. Gordian further maintains that the Medicare contractor's LCD L11449 did not reject the three disputed HCPCS billing codes until the LCD was revised as of January 2010. (See Pl. Opp. & Reply Brf. [Dkt. 56] at 9.) However, the MAC's final denial of coverage was not based on the LCD; instead, only CMS' July 2007 HCPCS Quarterly Update was relied on in the final agency decision.[6]

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[5] The Provider Reimbursement Review Board ("PRRB") reviews Medicare reimbursement appeals by hospitals and other providers. Decisions by the PRRB are subject to review by the Secretary's delegate, the Administrator of CMS. See Anaheim Mem'l Hosp. v. Shalala, 130 F.3d at 853. See also 42 U.S.C. § 1395oo(f)(1); 42 C.F.R. §§ 405.1871, 405.1875. Thus, when the Administrator of CMS issues a final decision on a provider reimbursement appeal, the prior decision of the PRRB is superseded. The same is true here; only the final decision by the MAC is at issue, and thus the prior ALJ decision and the contractors' reconsideration and redetermination on the same claims were superseded by the final MAC decision. 42 C.F.R. §§ 405.701(c), 405.720, 405.724.

[6] The Medicare contractor's LCD L11449 originally included (effective October 1, 1993) the three HCPCS codes at issue, A6200, A6201, and A6202. After coverage of surgical dressings billed under those three HCPCS codes was denied in CMS' July 2007 HCPCS Quarterly Update (effective July 1, 2007), the Medicare contractor made corresponding revisions to LCD L11449 (effective January 1, 2010). Thus, since the disputed surgical dressings were supplied in 2007 and 2008 and the three HCPCS codes were not removed from the contractor's LCD until January 2010, the MAC reasonably did not base its decision

11. Gordian's complaint about the Medicare contractor's Policy Article A24114 fails for the same reason. (See Pl. Opp. & Reply Brf. at 8-9.) The MAC denied coverage solely on the basis of CMS' July 2007 HCPCS Quarterly Update. The MAC's final decision was not based on the contractor's Policy Article or its prior Bulletin Article, neither of which specifically addressed Medicare "coverage."[7]

D. The Secretary's Final Decision Is Not Arbitrary and Capricious or Otherwise Contrary to Law.

12. Gordian argues that the MAC arbitrarily and capriciously failed to reach the supplier's allegations that the agency unlawfully revised the definition of "composite dressing" and deemed the three HCPCS Level II codes (A6200, A6201, and A6202) invalid for purposes of Medicare claims submission. (See, e.g., Pl. Op. Brf. at 16-22.) The Secretary responds that Gordian's challenge to the agency's HCPCS billing instructions and the fee schedule payment amounts can be raised as part of its reimbursement appeal. (Def. Suppl. Brf. [Dkt. 63] at 1.)

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on the LCD.

[7] The MAC did discuss the Medicare contractor's LCD and its Policy Article on surgical dressings, but the MAC was simply responding to Gordian's complaints about the reconsideration of its claims by the QIC and the ensuing rejection of Gordian's claims by the ALJ. (A.R. 8-9.) Specifically, the MAC explained that a facial challenge to an LCD must be brought through a different administrative appeals process, 42 C.F.R. Part 426, and that such LCD appeals cannot include issues about policy articles and billing codes. (A.R. 9.) The MAC's statements about the LCD and Policy Article and the separate appeals process for facial challenges to LCDs were not necessary to its decision because the MAC relied solely on CMS' July 2007 HCPCS Quarterly Update, which superseded both the contractor's LCD and its Policy Article. Similarly, since the MAC's final decision is not based on the contractor's Policy Article, the MAC's erroneous statement about the effective date of the Policy Article is harmless error. See Yassini v. Crosland, 618 F.2d 1356, 1362 (9th Cir. 1980) (a "hypertechnical" violation is not grounds to invalidate final agency action).

13. The Court concludes that Gordian's challenge to the agency's HCPCS billing instructions and the fee schedule payment amounts can be raised as part of a Medicare reimbursement appeal. If a supplier uses the three alternative HCPCS codes directed by the agency (A6251, A6252, and A6253) and coverage is found, then it would be paid the specific fee schedule amounts applicable to those three codes. However, the supplier could use the same administrative and judicial process, and argue that it was underpaid because it should have been permitted to use the three higher paying codes instead of the lower paying codes directed by the agency.[8] The statute would support the supplier's appeal because its challenge to the agency's billing instructions pertains to "the amount of benefits available." 42 U.S.C. § 1395ff(a)(1)(B). Further support is provided by the regulations, for the supplier's challenge to the billing instructions would "hav[e] a present or potential effect on the amount of benefits to be paid." 42 C.F.R. § 405.924(b)(12).

14. In addition, the Court is satisfied that the Medicare appeals adjudicators have the authority to decide the merits of Gordian's challenge to the agency's HCPCS billing instructions, and to which fee schedule payment amount (if any) applies to each claim at issue. The agency's billing instructions, in CMS' HCPCS Quarterly Update, its Transmittal 1388, the Medicare contractor's Bulletin Article, and its Policy Article, are subregulatory program guidance. The MAC, the ALJs, and the QIC "are not bound by . . . CMS program guidance, such as program memoranda and manual instructions." 42 C.F.R. §§ 405.968(b)(2), 405.1062(a). Since the appeals tribunals are not bound by the program guidance in the agency's HCPCS instructions, the adjudicators have the authority to decide the merits of Gordian's challenge to those instructions, and determine which fee schedule payment amount (if

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[8] The 2006 fee schedule amount for HCPCS code A6200 ranged between $8.08 and $9.50. The range for code A6251 was between $1.69 and $1.99. See https://www.cms.gov/MedHCPCSGenInfo/Downloads/HCPCSLevelIICodingProcedures7-2011.pdf

any) applies to each claim. Furthermore, there is no indication in the statute or regulations that the agency's subregulatory HCPCS billing instructions are not reviewable. See 42 U.S.C. § 1395ff(e)(1), (f)(8), (h)(6)(A) (specific matters that are not reviewable); 42 C.F.R. § 405.926 (same).

15. There also is no impediment to review of Gordian's challenge to the fee schedule payment amounts. Under 42 C.F.R. § 405.926(c), "[a]ny issue regarding the computation of the payment amount . . . of general applicability . . . such as . . . a fee schedule" is not an appealable initial determination. But Gordian has not challenged "the computation" of the payment amounts for its claims. Gordian's main complaint is that, when it used its preferred HCPCS codes, coverage was barred by CMS' HCPCS Quarterly Update, and so no reimbursement was owing. However, if Gordian used the appropriate HCPCS codes directed by the agency, Gordian could allege that it was underpaid because the fee schedule amounts for those codes are less than those for Gordian's preferred codes. Thus, Gordian could challenge *which* fee schedule payment *amount* (if any) should apply to a given claim — not "the computation" of a specific payment amount.

16. In American Medical Technologies v. Johnson, 598 F. Supp.2d 78, 82 (D.D.C. 2009), Gordian's predecessor-in-interest similarly contested "the Secretary['s] assert[ion] that plaintiff could have submitted claims for reimbursement using the new [HCPCS] codes rather than the old ones[,]" and that 42 C.F.R. § 405.924(b)(12) provided "a vehicle for administrative appeal" of the agency's HCPCS billing instructions. The district court rejected the supplier's "counter[,] that the Secretary's proposal is unworkable" due to 42 C.F.R. § 405.926(c), stating "[t]he Court is persuaded that . . .§ 405.924(b)(12) would provide plaintiff with a vehicle for administrative review and, moreover, review would not be barred by § 405.926(c)." Id. at 83 (footnote omitted). The Court concludes that the reasoning of the American Medical Technologies court applies equally to this case.

17. The regulations cited by Gordian are not to the contrary. Although 42 C.F.R. § 426.325(b)(4), (12) does remove certain matters from review, (see Pl. Suppl.

Brief [Dkt. 62] at 2), those matters are"not reviewable under this part." 42 C.F.R. § 426.325(b) (emphasis added). The "part" referred to in the foregoing regulation is Part 426 of Title 42 of the Code of Federal Regulations, which provides for administrative and judicial review of facial challenges to the lawfulness of a national coverage determination (NCD) or a local coverage determination (LCD). Id. § 426.100. However, this case does not involve any NCD, and Gordian has not challenged any LCD. On the contrary, the supplier alleges that "the controlling LCD actually supported Gordian's position that the old codes could be used." (Pl's. Suppl. Brief at 3.) Also, in the final agency decision, the MAC concluded that Gordian's appeal was based solely on the review provisions for individual benefit claims, and Part 426's separate provisions for appeals of NCDs and LCDs was inapplicable. (A.R. 6, 9.)[9]

18. Gordian's reliance on 42 C.F.R. § 426.325(b)(7) fails for the same reason. (See Pl's. Suppl. Brief at 4.) This regulation is part of Part 426's provisions for appeals of NCDs and LCDs, but Gordian has not brought a facial challenge to an LCD or an NCD.

19. Gordian's reliance on 20 C.F.R. § 404.946 is also unavailing. That provision is part of the regulations, in 20 C.F.R. Part 404, Subpart J, for appeals of claims for Social Security retirement benefits and disability benefits, and § 404.946 has no applicability to this case. For Medicare purposes, the 20 C.F.R. Part 404,

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[9] According to Gordian, "the ALJ and the MAC both stated erroneously that Gordian's objections could have been heard through the LCD appeal process set forth in 42 C.F.R. § 426.325." (Pl's. Suppl. Brief [Dkt. 62] at 3.) On the contrary, the MAC expressly *rejected* the notion that Gordian's challenge to the agency's billing instructions and fee schedule payment amounts could have been heard through the LCD appeals process. (A.R. 9 ("An LCD review is distinct from the claims appeal process in 42 C.F.R. part 405, subpart I, used here."). As for the ALJ, its interim decision on Gordian's nine claims at issue was superseded by the MAC's final decision on the same claims. 42 C.F.R. §§ 405.701(c), 405.720, 405.724. See also Homan & Crimen, Inc. v. Harris, 626 F.2d at 1205.

Subpart J regulations apply only to initial determinations and redeterminations by the Social Security Administration (SSA) as to whether a *person* is *entitled* to Medicare benefits. ALJ hearings on Medicare entitlement issues are governed by Medicare's own regulations in Part 405, Subpart I. 42 C.F.R. § 405.904(a)(1). In any event, this case involves only issues of Medicare *coverage and payment* for the Part B benefit claims of a *supplier*; this matter does not present any issues regarding a person's entitlement to Medicare benefits. See id. § 405.904(a)(2).

E. Gordian Cannot Supplement the Record at Trial, and The Secretary's Objections To Such Extra-Record Evidence Are Granted.

20. Gordian has submitted nine exhibits with its Opening Trial Brief comprising 120 pages, which would expand this record review matter beyond the 519-page certified administrative record that the Secretary has filed with this Court. The Secretary has timely objected to Gordian's extra-record evidence.

21. Gordian has made no showing that the certified administrative record is "so inadequate that judicial review would be 'effectively frustrated.'" Animal Defense Council v. Hodel, 840 F.2d 1432, 1436 (9th Cir. 1988), as amended, 867 F2d 1244 (1989). Therefore, since Gordian has not demonstrated that the record is inadequate, there are no grounds for allowing Gordian to expand the record by the introduction of, inter alia, expert witness testimony. Id.; see also Lands Council v. Powell, 395 F.3d 1019, 1030 (9th Cir. 2005)("Judicial review of administrative action . . . is supposed to . . . [proceed] on the basis of the administrative record" in the absence of certain exceptions.)[10]

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[10] After the Secretary answered the Complaint, Gordian filed a motion seeking discovery [Dkt. 41] in the form of interrogatories, requests for admissions, and document production requests. The Secretary opposed Gordian's discovery motion [Dkt. 46]. In a June 13, 2011 minute order [Dkt. 48], the Court denied Gordian's discovery motion, concluding that judicial review of the MAC's final decision is confined to the administrative record because Gordian had failed to establish any basis for extra-record discovery. For essentially the same reasons, the Court now rejects the nine extra-record exhibits submitted with Gordian's

22. Even assuming arguendo that Gordian could establish the requisite fundamental inadequacy in the administrative record, there still would be no basis to expand the record under the few circumscribed exceptions to the rule that judicial review must be limited to the administrative record. Lands Council v. Powell, 395 F.3d at 1030 (citing Animal Defense Council v. Hodel, 840 F.2d at 1436).

a. First, extra-record evidence is not necessary to determine whether the Secretary has considered all relevant factors and explained the final agency decision. The certified administrative record includes all of the materials considered by the MAC in finally denying coverage of Gordian's non-bordered composite dressings on the basis of CMS' July 2007 HCPCS Quarterly Update. See Asarco, Inc. v. U.S.E.P.A., 616 F.2d 1153, 1159 (9th Cir. 1980).

b. Second, Gordian has not alleged or even suggested that, in reaching its final decision, "'the agency has relied on documents or materials not contained in the record.'" See Animal Defense Council, 840 F.2d at 1436. Therefore, this exception also does not justify Gordian's attempt to expand the record in this action.

c. Third, "supplementation of the record is [not] necessary to explain technical terms or complex subject matter." Id. Here, the Secretary's final decision denied coverage on the basis of CMS' July 2007 HCPCS Quarterly Update, a provision that clearly sets forth its requirements. Finally, Gordian's prior allegations of agency "bad faith" are also devoid of merit.

23. For the nine claims at issue in this case, Gordian ignored the agency's directive to use "new" HCPCS billing codes; instead, it used the "old" codes. (Compl. at ¶ 50.) The Court has concluded that if Gordian had used the new codes and then argued that it was underpaid (because the fee schedule amounts for the new codes are less than those for the old codes), the MAC could have decided the merits of the supplier's challenge to the agency's billing instructions. In view of Gordian's refusal to use the new HCPCS codes, its attempts to expand this record review case

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by the introduction of, inter alia, expert witness testimony are improper, and the Secretary's objections to Gordian's proferred extra-record evidence are sustained.

24. The Secretary's final decision in this matter is devoid of legal error, supported by substantial evidence, and not arbitrary and capricious or otherwise contrary to law. Therefore, the Secretary's final decision is sustained by this Court.

DATED: April 4, 2012.

Christina A. Snyder
UNITED STATES DISTRICT JUDGE

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